PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Golds et al.

Serial No.: 10/716,639

Filed: November 19. 2003

For: MESH AND STENT FOR INCREASED FLEXIBILITY

Examiner: Ho, U.

Group Art Unit: 3738

Docket: 760-57RCE/CON

Dated: December 23, 2004

I hereby certify this correspondence is being deposited with United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 29, 2004.

Signature Kim Tillman/ Kim Tillman

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME A PATENT UNDER 37 C.F.R. §1.131

Sir:

1 I, Ellen Golds, a citizen of the United States, residing at 32 South Dr., Hastings-on-Hudson, New York, am the inventor of the above-identified application.

2. At the time of the invention thereof, I was an employee of Boston Scientific. The present application was assigned to Scimed Life Systems Inc. a subsidiary of Boston Scientific. I submit this Declaration to establish completion of the invention set forth in this application in the United States at a date prior to February 2, 1999, i.e. the effective date of U.S. Patent No. 6,398,803; to Layne et. al. (hereinafter the '803 patent) which was cited by the Examiner in an Office Action mailed December 17, 2002.

3. From the documents submitted herewith, and as set forth hereinbelow, it can be seen that the invention was completed in the Unites States before February 2, 1999, which is a date earlier than the U.S. filing date of the '803 patent. Completion of the invention prior to February 2,

1999 is shown by conception and actual reduction to practice of the invention as evidenced by prototypes, which were made in accordance with the claimed invention.

4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to February 2, 1999, the following documents are being submitted as evidence:

A. Meadox, Boston Scientific Corporation Invention Disclosure Pages 1-3 (Exhibit A) bearing a date signed by the inventor and a date signed by a witness prior to February 2, 1999, the earliest effective filing date of the '803 patent. The Invention Disclosure describes the conception of the device according to the claimed invention and a method of making same.

B. Meadox, Boston Scientific Corporation laboratory notebook pages 2, 7, 9-11; Book No. SA4, (Exhibit B) bearing a date signed by the inventor and a date signed by a witness prior to February 2, 1999, the earliest effective filing date of the '803 patent. The notebook page describes the claimed invention and method of making same. Additionally, experimental results for the actual reduction to practice of the claimed device describing the actual existence of the device in question, sufficient to work for its intended purpose.

5. The material submitted herewith establishes that the invention was complete, i.e. conceive and reduced to practice at a date prior to February 2, 1999, the filing date of the '803 patent.

6. This Declaration is submitted in response to an Office Action and is therefore believed to be timely filed.

7. I hereby declare that all statements made herein of my own knowledge are true and that

all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: December 23, 2004

Ellen Golds

INVENTION DISCLOSURE

INVENTOR NAMES *Please include full address on back*	LOCATION	EXT	DATE
Jeff Boatman, David Tseng, Ellen Golds	Meadox Medicals	738	

1. Appropriate Title of Invention:

Mesh ePTFE covering of endovascular stent grafts: methods to expose the stent knuckles

2. Summarize the device, method or process of the invention:

This invention describes methods how to expose the stent knuckles during ePTFE laminating of endovascular stent grafts. Three methods could be used to expose the knuckles:

A) After wrapping two layers of PTFE sheet on stent, a razor blade was used to slice the PTFE covering on the knuckles (1 mm length of opening), use razor blade to pull material back over bend, lift the knuckle, and insert the PTFE material under the stent knuckles. After knuckles were exposed, the stent graft assembly was sintered under sintering temperature.

B) After stent graft assembly was sintered under 680°F temperature, a razor blade was used to scrape the PTFE covering out of knuckles. Then re-sinter the stent graft assembly under 680°F.

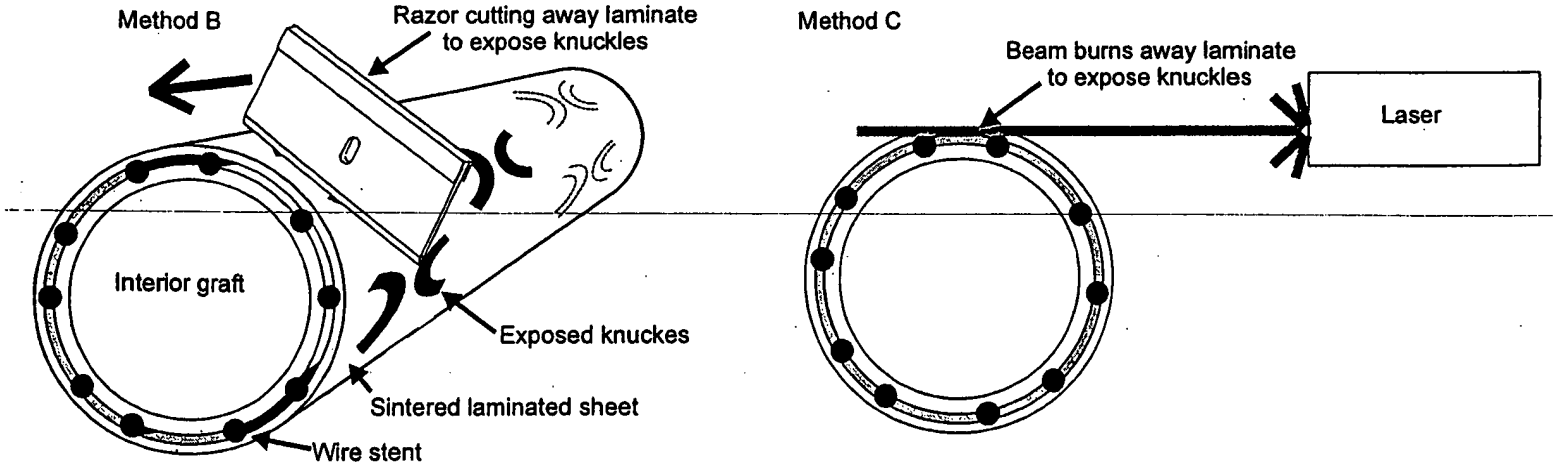
C) Use a cutting laser beam to cut PTFE material around the stent knuckles. Then a non-cutting tool could lift the knuckle up and insert the PTFE material underneath.

3. Briefly describe the advantage of this invention:

Using mesh ePTFE covering on stent grafts give stent grafts more flexibility as compared to total covered stent graft. The exposed knuckles allow more freedom of movement.

The methods described here are easy to operate, easy to scale up, and less time consuming than previous methods.

4. Sketch the invention:



(Method A not shown; similar to Method B except perform before sintering)

Meadox®
Boston Scientific Corporation

Witness:
Read & Understood

Patricia A. Murphy

Dated: 6

5. What is the development stage of this invention (check all that apply)?

- ☐ Conceptual/Unwritten
- X☐ Lab Book
- ☐ Verbally Disclosed ☐ In house ☐ Out of house
- ☐ Written Disclosure or Report ☐ In house ☐ Out of house
- X☐ Prototype or Empirical Experience
  - X☐ Bench ☐ Animal ☐ Clinical
- ☐ Actual Product, Method or Process

6. What is the current project phase?

- ☐ None; not an approved product
- ☐ Definition
- X☐ Design
- ☐ Development
- ☐ Manufacturing Scale-up

- ☐ Product/To be released: Date Europe Q4'98; U.S. 2000
- ☐ ☐ Product Released: Date_____

Please indicate the product name and number, if available:

7. Which division is sponsoring this project?

- ☐ Medi-Tech
- ☐ Microvasive Endo
- ☐ Microvasive Uro
- ☐ Other_____
- ☐ Maple Grove
- X☐ Meadox Medicals
- ☐ Sunnyvale

Name the marketing/engineering manager(s) championing this invention: Ellen Golds

8. **Name any key physicians interested in this invention:** N/A

9. **Describe any alternate embodiments or further features that could be included with this invention. If you think that the invention could be useful for other projects or divisions, please indicate so.**

Meadox®
Boston Scientific Corporation

Witness:
Read & Understood
Patricia A. Murph
Dated:_____
C

10. Indicate/attach any prior art that you are aware of (please include Boston Scientific work):

A prior invention disclosure about mesh ePTFE covering of stent graft was submitted by Ellen Golds et al.

Thank you for your completed invention disclosure. Please be sure to have the disclosure witnessed by a person who understands the invention, yet who is not an inventor or involved directly with the project. Please attach any notes, samples, specifications, drawings and prior art that may assist in the development of a patent application. Your disclosure will be reviewed by the appropriate Patent Review Board and you will be notified as to the decision to pursue or further develop this invention.

Witness:
Read & Understood

Patricia A. Murphy

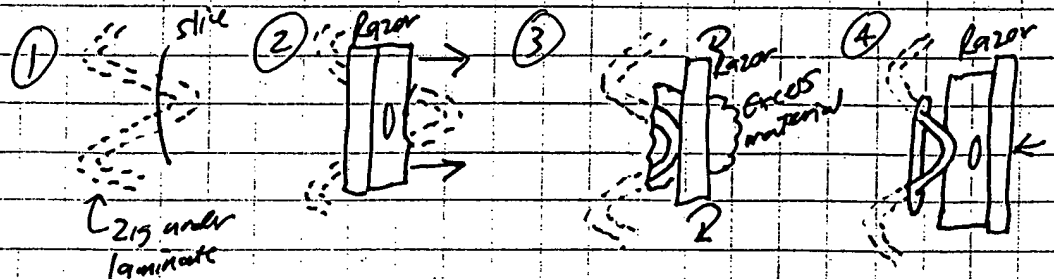
Dated:_____

Project No.

Book No. 44 TITLE Stent Laminating

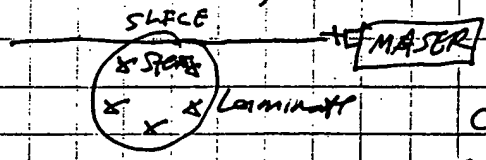
From Page No.

- Based on concept by D. Tseng. Wrap stent with two layers of laminating material, then slice material perpendicular to stent about 1mm below knuckle. Use razor to pull material back over bend, lift zig up enough so that material will slide back under zig.



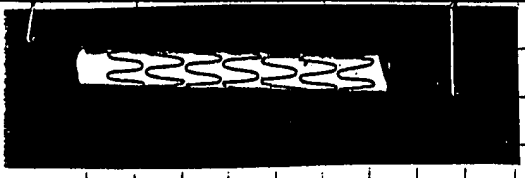
This is done for every bend except those along a spine. Experimentally, this appears to work well. The razor did nick the stent surface and sometimes left strands of connecting material. The operation really requires a wide-field microscope or the strands are too small to see unaided.

A laser/maser may be able to more cleanly cut the slice by melting the laminate tangentially.



Then a thin but non-cutting tool could lift the bend up or touch the cut material under it.

An experimental stent was made using the razor technique, 2μM laminate and 300μM tubing. The material was bonded in a 680°F salt bath for 1min 30 sec in packed salt and then 45 sec exposed. Preliminary observation are promising.



RS Boatman

10" or "3B Stent"

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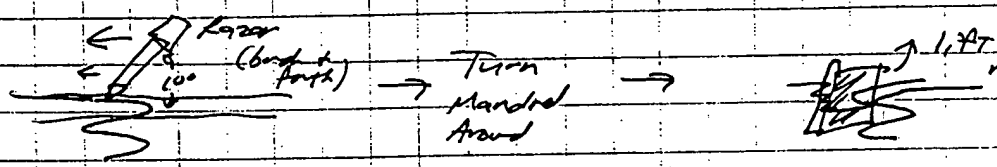
Witnessed & Understood by me	Date	Invented by RS Boatman/D. Tseng	Date

Page No.

Tried scraping material off of laminate prior to salt bath.

Method 1 -

Scraped material off by holding razor ~ 10° to stent after applying 2 wraps of 12μM PTFE. Instead of "tacking" under with razor at the same time, I did all knuckles in one orientation, turned the mandrel around, lifted each knuckle up, then scraped off the material in the other direction, turned the mandrel around, then lifted up the remaining knuckles. Only a light touch was used in scraping, and I employed a gentle, back-and-forth, gradually advancing motion.



I call this stent S44-7A.

Method 2 - Same as method 1 but without turning the mandrel around and lifting up the knuckle (ie, scraping only). I call this stent S44-7B. Suggested by E. Golds

I bonded these by submersion in a 680°F salt bath for 2'30" in packed salt, then exposed for 45 seconds.

S44-7A (material scraped then tacked) - material was not bonded on several knuckles. Unclear if this is a problem.

S44-7B (not tacked) - Material bonded nicely but some knuckles not exposed.

The separation of material @ knuckles may be due to the packing technique used to fill the shrink tubing with salt.

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Read & Understood by me,	Date	Invented by	Date

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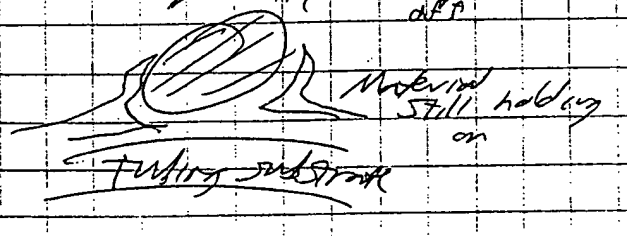
Another design - 6mm sutured + spine (welded spine not available). Placed over 100μM tubing and covered w/2-layers of 12μM (2μM pore) PTFE & sintered for 2'95" (@680°F). Then, after removal from salt pack & rinsing, I scraped the laminate from the knuckles (except at the spine). I found the scraping much easier than with the samples which were scraped pre-sintering. However, attempts to lift the knuckles up were frustrated because the underlying laminate was now bound to the wire



Attempts to free the wire caused the laminate to start tearing.

Also, while the laminate scraped off much more easily, it formed small "corkscrews" of material along the edge of the razor passed over.

I call this Stent 544-9. I finished sintering at 4:31 / 680°F. It was very flexible although the outermost layer mostly melted. The laminate material was initially attached to the wire, but after some manipulation it mostly freed itself.

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essed & Understood by me,	Date	Invented by	Date

Project No. _____
Book 3. _____ TITLE Laminated Stent Design

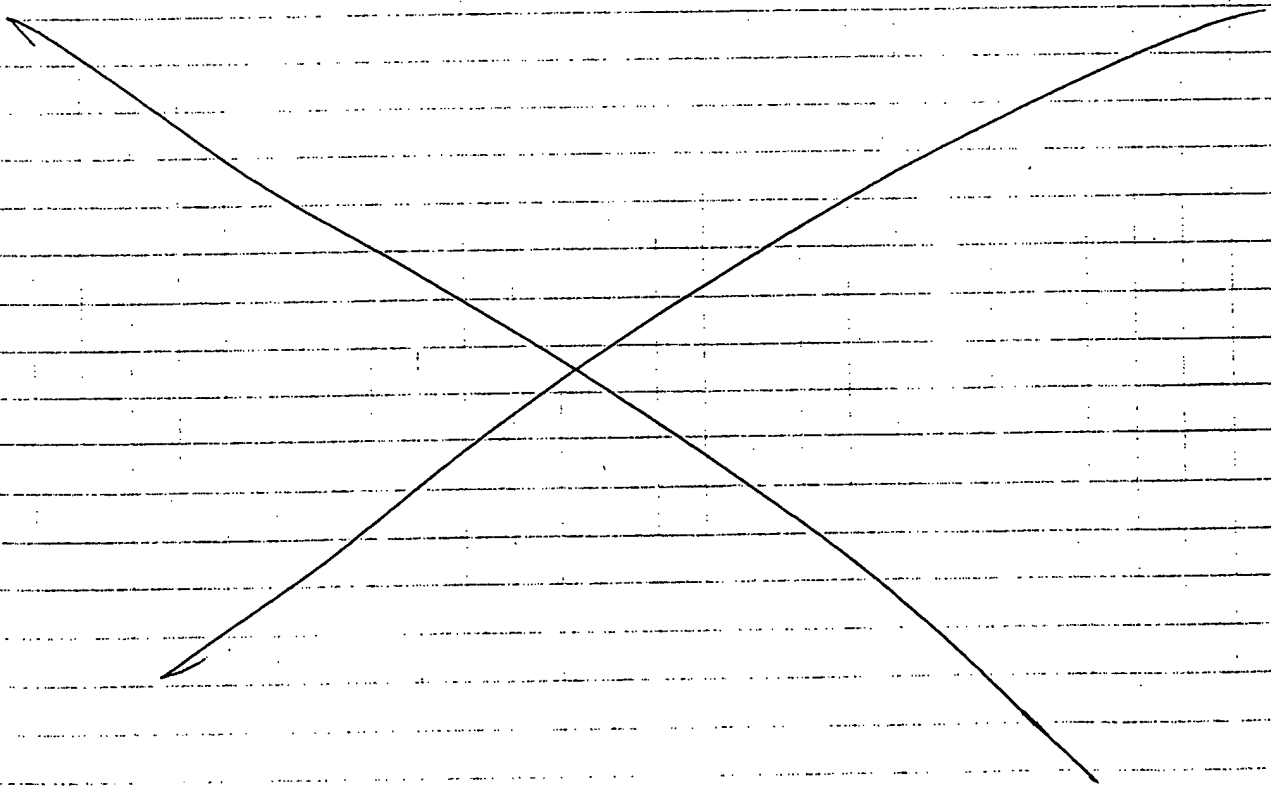
From Page No. __

Another design. Prototype designated as S44-10.
Wrapped 9 sutured stent in 2-plies of 12μM PTFE; underneath over a 500% expansion (~200μM) tube. The sutures had all been removed except along the spine, those sutures were reinforced with a drop of cyanoacrylate to duplicate a weld.

Semi-sintered for 45" @ 680°F. The laminate was only averagingly sintered, in fact the seam lifted up simply by running water over the stent. I then scraped off the laminate & tested the material underneath. It was very weak and formed many stray filiments.

I then packed it in salt again, shrink-wrapped it, shrunk down the tubing with a heat gun, then shrink-wrapped it a second time. I sintered it for 2' @ 680°F (actual temp ~650°)

The final stent was very flexible but had loose flaps of material on it



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Witnessed & Understood by me,	Date	Invented by	Date

Comparison of Stents

Page No.

Note: these stents were made using hollow steel mandrels

Objective: to demonstrate at what point during the sintering process is optimal for uncovering the stent knuckles.

First prototype designated 544-11. Each 8-knuckle (5cm) sutured stent was glued the suture along the spine, then cut & removed all other sutured. Ultrasonic cleaned in IPA, placed over 5000 expanded (~150 μM) tubing, placed two wraps of 12μM sheet over it. I then trimmed away the sheet over the knuckles as per pg 7 Method 2, except for knuckles along the spine and the first two rows at either end.

It was extremely difficult to trim back the material as it kept sliding away. In particular extensive manipulation was needed near the seam because the seam kept coming up or bunching up.

I then packed it with salt & heat-shrunk the tubing around it. On Bill K.'s suggestion, I let the mandrel cool and then heat-shrunk it again.

The second prototype, designated 544-11A, was identical to 544-11 except that it was fully sintered (~650°F / 2'45") before scraping the knuckle. Both -11 and -11A were subsequently re-sintered, without the salt pack, for 45 seconds.

The third prototype designated 544-11B, was also the same, but was sintered in salt for 1'20", the knuckles scraped, repacked in salt, re-sintered for 1'20", removed & washed, trimmed, then final hot-salt dipped for 45".

Note: due to non-use of IPA, these stents were removed from mandrel by chilling mandrel & causing it to shrink.

Note: The pre- and during- scraping included "pushing" the material under the stent bends

Note: Using a hollow mandrel requires great caution during quenching, as the cold water rushing into the hot tube creates flash steam.

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